Citation:

Vessey JA, Sherwood JJ, Warner D, Clark D. Comparing hand washing to hand sanitizers in reducing elementary school students' absenteeism. *Pediatric Nursing* 2007; 33 (4): 368-372.

PubMed ID: 17907739

Study Design:

Randomized crossover trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare the efficacy of a hand sanitizer to standard hand washing in reducing illness and subsequent absenteeism in school-age children.

Inclusion Criteria:

Second and third grade students attending seven elementary schools in the Butte, Montana School District.

Exclusion Criteria:

- All students in the designated grades were eligible to participate
- Those who did not give consent had allergies to soap, hand sanitizers or one of their components.

Description of Study Protocol:

Recruitment

Students attending one of seven elementary schools in the Butte, Montana School District enrolled in the second or third grade were eligible to participate in the study.

Design

Randomized, crossover trial.

Blinding Used

No blinding was used.

Intervention

- The month prior to data collection, a school nurse with content expertise, but no affiliation with the school district data collectors, taught the students in each classroom correct hand washing and sanitizing procedures using standard curriculum including the video "Wash those Hands." No additional formal education was provided
- Data collection was split into two phases: January and February (phase 1) and March and April (phase 2). These time periods were selected to minimize the effects of holidays and vacations on illness communicability
- The classrooms were divided into two cohorts. Cohort 1 (N=191) consisted of nine classrooms and cohort 2 (N=192) also consisted of nine classrooms. Each cohort was assigned to one of the two treatments (hand washing or hand sanitizing) during each phase of the study. Appropriate product (soap or hand sanitizer) was provided in the classrooms and restrooms during this time period. Teachers reminded students to wash or sanitize their hands as they normally would and a strict reminder protocol was not used.

Statistical Analysis

Students' T test was applied to compare the number of student absences in each group.

Data Collection Summary:

Timing of Measurements

Absentee information was collected by school secretaries through the duration of the study. Secretaries were instructed to specifically ask whether the absence was due to acute, communicable illnesses for students in study classrooms.

Dependent Variables

Student absences, reported by secretaries.

Independent Variables

The use of hand washing with soap and water or the use of hand sanitizer throughout the school day.

Control Variables

None reported.

Description of Actual Data Sample:

- *Initial N:* 18 classrooms were targeted for inclusion in the study
    - There were 383 students enrolled in these classrooms
    - Written consent from parents or guardians and verbal assent from the student was obtained for 363 students
- *Attrition (final N):* Three students withdrew from the study because either the soap or hand sanitizer was too irritating
- *Age:* Students were enrolled in either the second or third grade
- *Ethnicity:* Not reported
- *Other relevant demographics:* Not reported
- *Anthropometrics:* Not measured

- *Location:* Butte, Montana School District.

Summary of Results:

Key Findings

- No significant differences were noted between the groups, indicating that the number of student absences was not appreciably affected by hand-cleansing technique used
- Mean differences in number of days absent between the soap and water and hand sanitizer groups were:
  - Soap and water (18 classrooms): 25.44 (Mean), 10.27 (SD), T=0.664, df=34
  - Hand sanitizer (18 classrooms): 26.77 (Mean), 7.00 (SD)
- A follow-up focus group comprised of teachers and school nurses indicated that hand sanitizers were preferred over soap and water.

Author Conclusion:

- Although additional large, well-designed clinical trials with longitudinal follow-up to measure sustained behavior change still need to be conducted, hand sanitizers are a viable alternative to routine hand cleansing using soap and water
- As schools are being called upon to increase surveillance for infectious diseases and mount prevention campaigns, hand sanitizers can play an important role in this effort.

Reviewer Comments:

Authors note the following limitations:

- *No true control group was used, it is possible that there was insufficient statistical power to detect a significant difference between the groups*
- *Obtaining accurate data for absenteeism due to communicable illness was difficult, even when parents were aware of the reason for providing accurate information*
- *The study was designed to look at ordinary usage of hand washing and hand sanitizing throughout the school day. Many other studies that report significantly less absenteeism were designed to include additional cues or adult supervised sanitizer use throughout the day*
- *A focus group of 13 school personnel was conducted at the end of the study to elucidate participants' experiences with soap and water and hand sanitizers.Many of the participants' observations indicated that they preferred the use of the hand sanitizer over soap and water, as it better matched the pragmatics of the school day. The amount of time required was a key consideration.*

In addition:

- *The investigators report randomizing the classrooms to treatment regimen, but the methods are not reported. The number of students in each groups was nearly identical despite entire classrooms being randomized adding to the suspicion that the groups may not have been truly randomized (although this effect is minimized with the cross-over design).*
- *The students were educated on appropriate hand washing and sanitizing techniques prior to the start of the study.The education (and the fact that the students knew they were being*

monitored by giving assent to participate) could have influenced how often and how well the students washed or sanitized their hands. This may have had an effect on absenteeism. A control group of students and classrooms that received no instruction would have been useful in the analysis.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	???
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes

3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes

6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	N/A
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A

	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	N/A
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes